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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,117	10/06/2005	Susan Banbury	03762.015700	2448

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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
12/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,117	BANBURY ET AL.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/2/09;10/26/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-18 are pending. Claims 3-10 and 12-18 are currently amended.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on 2/2/09 and 10/26/05 are acknowledged and have been reviewed.

Claim Objections

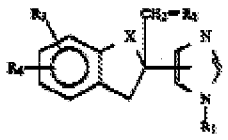
3. Claim 4 is objected to because of the following informalities: A claim cannot depend on it self. Appropriate correction is required. To expedite prosecution it is interpreted as claim 4 depends on claim 3.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-4, 12-15 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Karjalainen et al. (US 5,292,887).

Karjalainen discloses a solid dosage form of a compound containing formula I,  wherein Karjalainen teaches that X represents CH_2 or CHO, (i.e., Y in the instant application) one of R_3 or R_4 represent H, methyl, ethyl, methoxy, hydroxyl, or Halogen (i.e., R_1 and R_2 in the instant formula I), in a pharmaceutically acceptable acid salt such as chloride (see abstract as required by instant claims1 and 12-18 and col. 5, lines 25-27), as to promote pre-gastric absorption of the active ingredient as intended use. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Also, Karjalainen discloses a solid dosage form of the composition; it is inherent that the exposure to bile juices would fast disperse the solid dosage form.

As to instant claim 3, the recitation of the fast solid dosage form comprising a network of active ingredient and a water-soluble or water dispersible carrier which is inert towards the active ingredient, “the network having been obtained by subliming solvent….” is giving no patentable weight because the claim is to a solid dosage form, and therefore how it’s been

prepared carries no weight. Also, with instant claim 4, Karjalainen discloses that a solid dosage form inherently would comprise one or more matrix forming agents because these compounds are employed with pharmaceutically acceptable carriers (see col. 5, lines 25-26).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a

later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3 and 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karjalainen et al.

Karjalainen et al. is applied here as above in para 4.

However Karjalainen fails to teach that the halogen is a fluoro (as required by instant claims 16 and 17).

However, it is known in the art that F, Cl, Br and I are halogens, therefore, the generic teaching of halogens encompasses F, Cl, Br and I. Hence, taking the teaching of Karjalainen, one of ordinary skill in the art at the time the claimed invention was made would have expected to use any of the halogens to form the halogenated compound for the treatment of diabetes as taught by Karjalainen (see abstract).

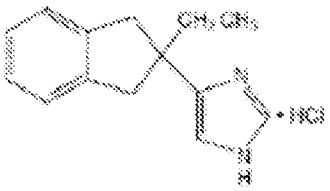
Claims 1, 4-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karjalainen et al. (US 5,292,887) in view of Linnoila et al. (US 4,968,692).

Karjalainen et al. is applied here as above in para 5. Additionally Karjalainen teaches that these compounds are employed with pharmaceutically acceptable carriers (see col. 5, lines 25-26).

However Karjalainen fails to teach that the fast-dispersing, solid dosage form comprises a network of active agent's which are water soluble or water-dispersible carriers (as required by instant claims 4-6 and 8).

Linnoila et al is introduced to show compounds of structural similarity to Karjalainen's compound may be in a tablet form and may contain pharmaceutically acceptable carriers such as gelatin and mannitol.

Linnoila et al. teach a similar drug formulation such as (i.e., atipamezole



, wherein Y represents CH2, (i.e., Y in the instant application R3 is ethyl and R 1,2 are hydrogen's see above formula), that are capable of being administered as a tablet (see abstract, col. 1, lines 30-33 and col. 5, lines 27-33, as required by instant claims 1, 12, 17-18). Additionally, Linnoila et al. teach that the tablet may be formulated with additives such as mannitol and gelatin (as required by instant claims 4-6 and 8; see col. 5, lines 43-50).

Since both Karjalainen and Linnoila teach the use of pharmaceutical carriers, one of ordinary skill in the art would have had a reasonable expectation that the base teaching of pharmaceutically acceptable carriers to include gelatin and mannitol as taught by Linnoila et al. It would have been obvious to one of ordinary skill in the art to employ the specific pharmaceutically acceptable carriers such as mannitol and gelatin as taught by Linnoila, because both Karjalainen and Linnoila teach structurally similar drugs.

6. Claims 1-6 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karjalainen et al. (US 5,292,887) in view Johnson et al. (US 6,316,027).

Karjalainen et al. is applied here as above in para 5.

However Karjalainen fails to teach a fast dispersing solid dosage form which is capable of disintegrating within 10 seconds of being placed in the oral cavity and also fails to teach that the matrix forming agent includes an amino acid (as required by instant claims 2 and 5-11)

Johnson et al. is introduced for its teaching of fast-dispersible solid dosage forms comprising gelatin, mannitol, and an amino-acid.

Johnson et al. teach a pharmaceutical composition for oral administration consisting essentially of a gelatin, a carrier, a solvent, and, an active ingredient (i.e., a dopamine agonist) in a form of a solid, fast-dispersing dosage form capable of promoting pre-gastric absorption of the active ingredient (see abstract, col. 3, lines 35-40) comprising a network of active ingredients and a water-soluble or water dispersible matrix which is inert towards the active ingredient wherein the network having been obtained by subliming solvent from the composition in the solid state (as required by instant claim 3, see abstract).

Johnson further teaches that the dosage is designed to completely disintegrate within 1 to 30 seconds of being placed in the oral cavity (as required in parts of instant claims 2-3) for the treatment of Parkinson's disease. Johnson also teaches that the matrix may include an amino acid (i.e., glycine), gelatin,

mannitol and a cyclic sugar such as cyclodextrin (see col. 6, lines10-30 as required by instant claims 4-11).

It would have been obvious to one of ordinary skill in the art to modify the solid dosage form of Karjalainen and incorporate Johnson's fast dispersing solid dosage form because Johnson teaches that these fast dispersing forms are particularly advantageous to patients with swallowing difficulties and are further advantageous because they can be easily disintegrate rapidly in the mouth, thus, minimizing the need of large volumes of water (see col. 3, lines 50-55).

7. Claims 1-18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Karjalainen et al. (US 5,292,887 in view of Murray et al. (US 6,709,669).

Karjalainen et al. is applied here as in ¶ 5 above. Karjalainen also teaches the drug is used for the treatment of diabetes (see abstract)

However Karjalainen et al. fails to teach the limitations of claims 2 and 5-11. Therefore Murray is added to show that fish gelatin is known in the art for use in fast dissolving dosage formulations.

Murray teaches a pharmaceutical composition comprising a carrier and an active ingredient (e.g., drug, compound, and the like) wherein the carrier is fish gelatin and the composition is in the form of a fast-dispersing dosage form which releases the active ingredient rapidly on contact with a fluid (e.g., saliva, bodily fluids, water, and the like). Preferably, the composition is designed for oral administration and releases the active ingredient rapidly in the oral cavity within 1-10 seconds, wherein the network having been obtained by subliming solvent

from a composition in the solid state containing the active ingredient and a solution or dispersion of the carrier in a solvent (see Abstract, and column 3, lines 50-55 and col. 4, lines 1-5, as required by instant claims 1-3). Murray's composition further comprises gelatin, wherein the gelatin is fish gelatin, mannitol, cyclic sugars, amino acid (i.e., glycine) as required by instant claims 4-11 (see col. 5, lines 24-44). Murray further teaches that the active agent may be an anti-diabetic drug (see col. 6, lines 10-11)

It would have been obvious to one of ordinary skill in the art to expand the composition formulation taught by Karjalainen et al., to include a fish gelatin because Murray teaches that fish gelatin is advantageously used in rapid disintegrating dosage forms because it rapidly releases the active agents (see col. 3, lines 21-24). It would have been obvious to one of ordinary skill in the art to employ Karjalainen anti-diabetic drug in the fast dispersible solid dosage form of Murray because Murray teaches that anti-diabetic drugs may be used in formulating such fast dispersible solid dosage drugs.

Double Patenting

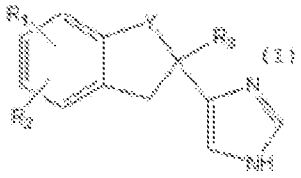
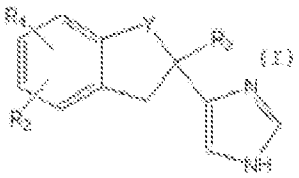
8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23 and 25-33 of U.S. Patent Application No. 10/534,091. Although the conflicting claims are not identical, they are not patentably distinct from each other. The reasons are as follows:

The claims of the instant application '117 are to a fast dispersing solid dosage form containing an active ingredient  that is capable of disintegrating within 10 seconds of being placed in the mouth and the claims of the copending application '091 are to administering a formulation comprising  via oromucosally (i.e., via the mouth through the mucosa membrane, i.e., fast dispersing).

Both applications recite using the same compositions and/or derivatives thereof. See current application claims 1-19 and copending application claims 23 and 25-33.

As to the copending application claims 23 and 25-33, these claims refer to administering the claimed active drug via oromucosally which is placing the solid form of the drug in the mouth to disintegrate (see copending claim 23).

One of ordinary skill in the art would have been motivated to use the copending application claims in producing the instant recited claims because both sets of claims are to a formulation that is capable of being dissolved/disintegrated when placed in the oral cavity via the mucosal membrane. Therefore the claimed formulation of instant claims 1-18 would have been used in producing the formulation in the copending claims or visa -versa

and therefore are part of the obvious variation of the copending application claims compared to the current application claims.

In view of the foregoing, the copending application claims and the current application claims are obvious variations of each other.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service

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9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
12/3/09

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618